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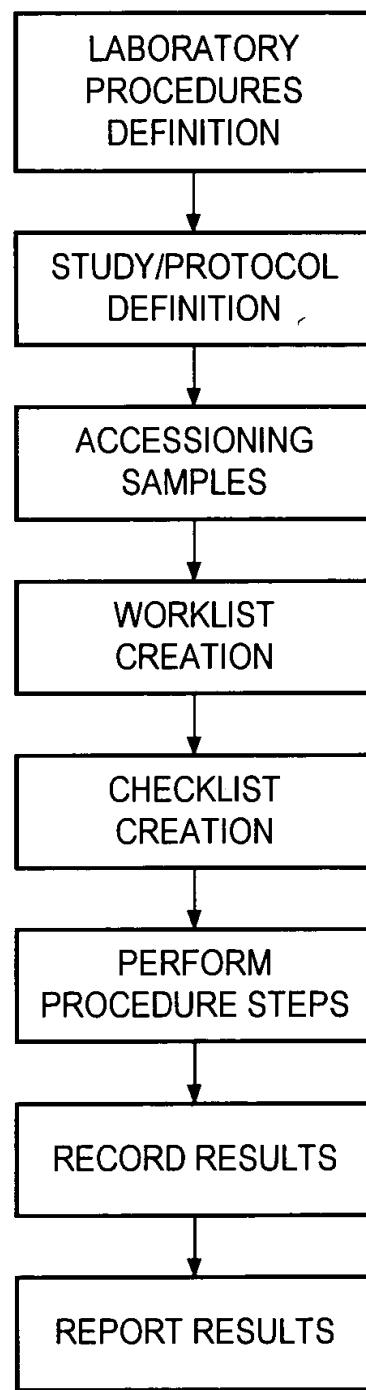


FIG. 1

T 02040 "ET 99E2E0

Study Setup

Clinical Study Definition

- Describes Sponsors & Investigators
- Declares Subject Attributes to Capture
- Associates Specific Lab Procedures with a Clinical Study
- Defines Genotype Results to Report

The screenshot shows a software interface for study setup. On the left, a tree view shows 'Study Protocols' expanded, with 'Sponsor Company' selected. The 'Sponsor Company' section contains fields for 'Study Number' (632-001), 'Sponsor Study Number' (198-005), 'Sponsor' (A Co., John Doe, Ph.D.), 'Sponsor Representative' (B Co., Jane Smith), and 'Sponsor Contact' (C Co., David Jones). Below this is a large, mostly blacked-out area. The 'Subject Attributes' section is expanded, showing fields for 'Protocol Title' (Pharmacokinetic Evaluation of Qinat(R) (oxatulyl an chlortilde) and IR oxybutyn in Administered Alone and in the Presence of Ketoconezole), 'PPG Protocol Title' (Genomic DNA isolation and molecular genotyping analysis of CYP2D6 A*1B*1D*1E*1C*1 and T*1 alleles), 'Procedures' (Edit Procedures), and 'Subject Attributes' (Edit Subject Attributes). The 'Subject Attributes' section includes fields for 'Subject Number', 'Gender', 'Birthdate', 'Ethnicity', and a 'Barcode' section with fields for 'Barcode Accession Number' (105881438), 'Barcode Length' (13), and 'Barcode' (100109912021). At the bottom are buttons for 'New', 'Save', 'Modify', 'Delete', 'Cancel', and 'Close'.

Fig. 2

Accessioning

Clinical Sample Registration

- Provides Validation Checks for Accession & Tube ID's
- Accommodates Multiple Sample Tubes
- Enforces Controlled Subject Attribute Terms
- Supports Sample Workflow

Accessioning

Study No.	Accession No.	Sponsor Sample Tube ID	Sample Tube ID	Received Date	Location
632-001	A100123	BA10112	PS2156	09-OCT-1998	
632-001	A100124	BA10113	PS2157	09-OCT-1998	
632-001	A100125	BA10114	PS2158	09-OCT-1998	
632-001	A100126	BA10115	PS2159	09-OCT-1998	

Print **Save As A Worklist** **Query**

PPGx Study No. **322001** **Sponsor:** **ACG, John Doe, Ph.D.** **Date Received:** **09-Oct-1999** **Sample Type:** **Fresh Whole Blood**

Accession No. **A100126**

Sponsor Sample Tube ID: **BA10115** **Sample Tube ID:** **PS2159**

PPGx Sample Tube ID: **PS2159**

Sample Tube Volume: **>5**

Sample Condition: **Good**

Comment: **Subject Attributes:** **Subject Number:** **15678**

Gender: **M** **Place Samples**

Birthdate: **18-Sep-88**

Ethnicity: **Black**

Save **New** **Cancel** **Modify** **Close**

Add Comments **Modified**

Created: **10/29/2013** **DNALIMS**

Fig. 3

Sample Tracking

- ◆ Supports Multiple Container Classes
- ◆ Allows User Defined Container Geometries & Templates
- ◆ Maintains Sample & Container Location
- ◆ Permits Flexible Sample Loading & Rearrangement
- ◆ Tracks and Maintains Container & Sample Ownership

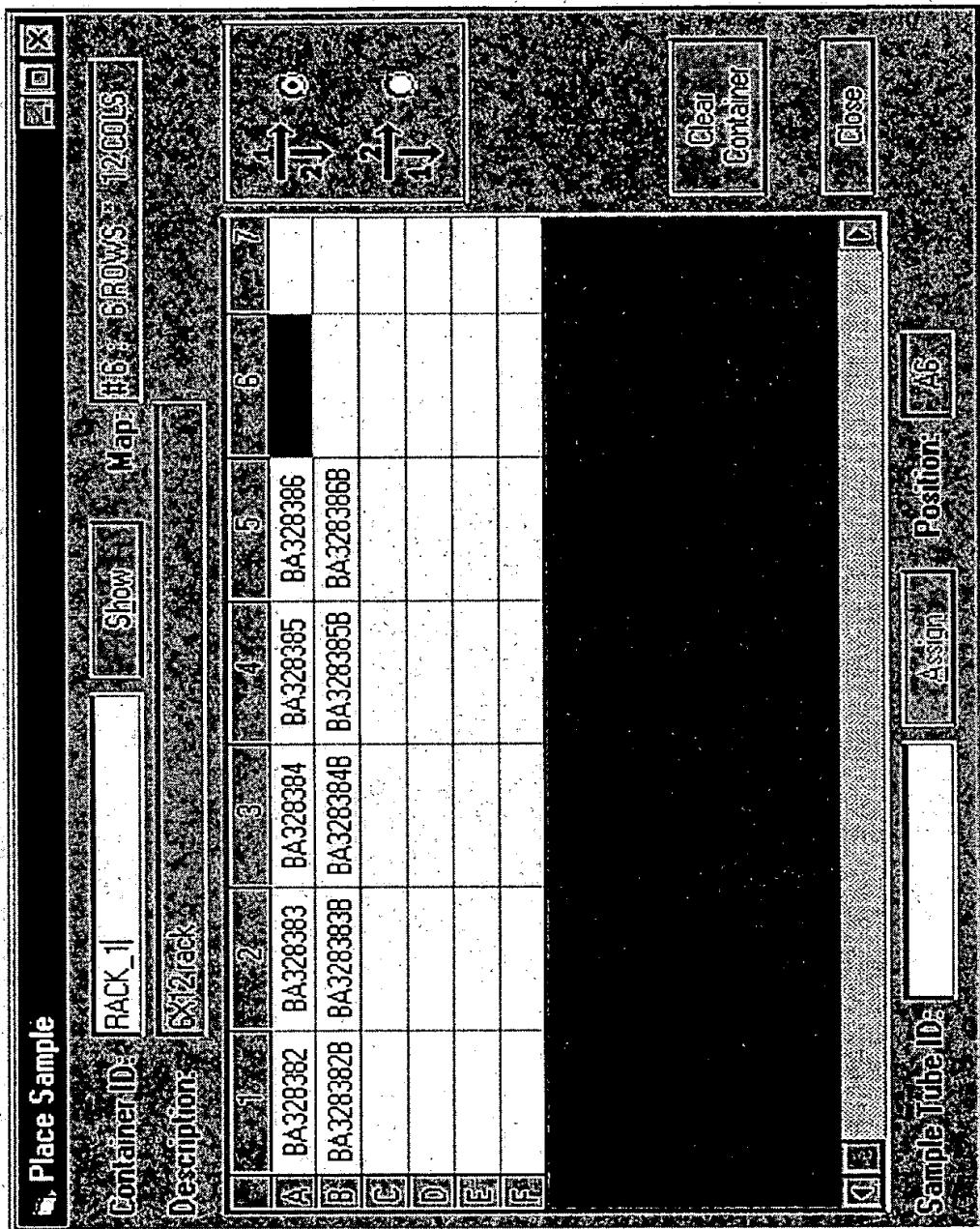


Fig. 4

Worklists

Worklist Name	Assigned To	Created By	Created On	Mo	Mo
POE 005	DNALIMS	DNALIMS	10/5/99 13:54	DN	DN
PS1SAMPLES	DNALIMS	DNALIMS	10/6/99 08:02	DN	DN
TODAYSGENOTYPING	DNALIMS	DNALIMS	10/6/99 17:47		

New

Worklist Name: PS1SAMPLES Assigned To: DNALIMS

Samples

Sample Label ID	Accession#	Prev Study No.	Location
S1	A1	PS1	Fr.1 Comp. Shelf Rack
S2	A2	PS1	Fr.1 Comp. Shelf Rack
S3	A3	PS1	Fr.1 Comp. Shelf Rack
S4	A4	PS1	Fr.1 Comp. Shelf Rack
S5	A5	PS1	Fr.1 Comp. Shelf Rack

CONTAINERS

#	R1
1	

Check In

Check Out

Open Checklist

Edit Worklist

Clear Worklist

Close

Container: C-01 Sample

Created: 10/6/99 08:02 Modified: 10/6/99 08:05

DNALIMS

Sample Worklists

- ◆ Named Sample Collections
- ◆ Assignable to Lab Scientists
- ◆ Groups Samples for Common Lab Operations
 - Location
 - Check-in/Check-out
 - Lab Procedures

Fig. 5

Electronic Procedure Checklists

- Supports Standard Operating Procedures
- Maintains Uniform Laboratory Processes
- Records Chain of Custody
- Tracks Repeat Operations

Fig. 6

PROCEDURES															
Procedure		Status	SOP Number	SOP Version											
DNA Isolation, 3 ml whole blood, Purgene Kit	APPROVED	GEN9709	C												
2D6 Allele "A" Identification	APPROVED	CYP2D6A	A												
SpectroMax DNA quantitation	APPROVED	MAX9802	A												
CYP2C9*3	APPROVED	CYP2C9-3	A												
CYP2C9*2 Ver. 7	APPROVED	CYP2C9-2	A												
CYP2C9*2 Ver. 6	APPROVED	CYP2C9-2	A												
Procedure Name:															
2D6 Allele "A" Identification															
Procedure Description:															
Laboratory Protocol for identification of CYP2D6 "A" Allele by RFLP-PCR															
Genes:	Alleles:														
<table border="1"> <tr> <td>SOP Number:</td> <td>CYP2D6A</td> </tr> <tr> <td>SOP Version:</td> <td>A</td> </tr> <tr> <td>Status:</td> <td>APPROVED</td> </tr> <tr> <td colspan="2"> <input type="button" value="New"/> <input type="button" value="Save"/> <input type="button" value="Cancel"/> </td> </tr> <tr> <td colspan="2"> <input type="button" value="Modify"/> <input type="button" value="Delete"/> <input type="button" value="Close"/> </td> </tr> </table>						SOP Number:	CYP2D6A	SOP Version:	A	Status:	APPROVED	<input type="button" value="New"/> <input type="button" value="Save"/> <input type="button" value="Cancel"/>		<input type="button" value="Modify"/> <input type="button" value="Delete"/> <input type="button" value="Close"/>	
SOP Number:	CYP2D6A														
SOP Version:	A														
Status:	APPROVED														
<input type="button" value="New"/> <input type="button" value="Save"/> <input type="button" value="Cancel"/>															
<input type="button" value="Modify"/> <input type="button" value="Delete"/> <input type="button" value="Close"/>															
Created	DNALIMS	Modified	DNALIMS	10/5/99 10:59											
	10/4/99 12:02														

Fig. 7

Procedure Steps

- ◆ A Single Step in a Lab Procedure
- ◆ Multiple Types:
 - Transfer
 - Dilution
 - Concentration
 - Adjustment
- ◆ Sample Preparation
- ◆ Highly Customizable
- ◆ Plug-in Architecture to Add New Types
- ◆ Interfaces to Automation

Procedure Steps

Procedure: DNA Isolation, 3 mL whole blood, Purgene Kit

Step	Step Input Type	Functional Type
Draw 10 mL of blood to a glass tube	CheckBox	Functional
Gently mix sample	CheckBox	Functional
Transfer 3 mL of blood to a glass tube	CheckBox	Functional
Add 9 mL of RBC lysis to RBC lysis tube	CheckBox	Functional
Mix and incubate 10 minutes at room temperature	CheckBox	Functional
Centrifuge 10 minutes at 3000 RPM	Text	Reagent Addition
Pour off supernatant into biohazardous waste container	CheckBox	Transfer
Resuspend pellet by vortexing	CheckBox	Reagent Addition
Add 3 mL of TE lysis Solution	Text	Transfer
Sample can be stored for 18 months at RT in Cell	Informational	Reagent Addition
PRINT	Informational	Reagent Addition

Step: Add 3 mL of RBC lysis to RBC lysis tube

Step Type: Informational Functional

Sample: CheckBox Text

Reagent Addition: CheckBox Text

Volume: 3000

Volume optional:

Wave scanning:

Loc. Parameters:

Save Sequence:

New:

Save:

Delete:

Cancel:

Modify:

Close:

Created: 3/30/99 08:00

Modified: 3/30/99 14:42

Close:

DNAIMS: 3/30/99 14:42

Fig. 8

Genotype Results

- ◆ Accommodates Values for Multiple Genes, Alleles & Assays
- ◆ Provides Master Review by Accession Number
- ◆ Supports Acceptance & Final Approval by Study Director
- ◆ Imports Results Electronically or Manually

Results

Study Protocol	Accession No.	Status	Entered On	Entered By			
PS1	A3	OPEN					
PS1	A4	OPEN					
PS1	A5	OPEN					
PS1	A6	OPEN					
PS1	A7	OPEN					
PS1	A8	OPEN					
PS1	A9	OPEN					
Accession No:	A6	Status: OPEN					
Genotyping	DNA Purification	Chain Of Custody					
GENE	Status	Interpretation	Exclude	Final GT	Entered On	Entered By	
CYP2C9	COMPLETE	EXTENSIVE METABOLIZER	<input type="checkbox"/>	wtA	DNALIMS	10/6/99 6:48	
Gene	CYP2C9						
Allele	Result	Batch	Procedure	Created By	Entered		
m2	ml/wt		CYP2C9 Ver. 7	DNALIMS	10/6/99 6:09 48 PM	DNALI	
m2	ml/wt		CYP2C9 Ver. 7	DNALIMS	10/6/99 6:09 48 PM		
m2	ml/wt		FINAL RESULT				

Fig. 9

Auditing

- ◆ Track Changes in Database
 - Study
 - Lab Procedures
 - Sample Results
 - Flexible Audit Reporting
- ◆ Chain of Custody by Accession
- ◆ Evaluation of

Audit Report

Protocol Audit Trail

STUDY_PROTOCOL	AUDIT_ID	PROTOCOL_ID	SPONSOR_STUDY_PROTOCOL_TITLE	PROX_STUDY	PROX_PROTOCOL_TITLE	CREATED_BY
	885	61	AIA	Evaluation of STUDY-1	X	DNALIMS
-	886	61	AIA	Evaluation of STUDY-1	X	DNALIMS
-	891	61	AIA	Evaluation of STUDY-1	X	DNALIMS
-	891	61	AIA	Evaluation of STUDY-1	X	DNALIMS
-	893	61	AIA	Evaluation of		DNALIMS
-	897	61	AIA	Evaluation of		DNALIMS
-	900	61	PHO-001	Evaluation of		DNALIMS
-	904	61	PHO-001	Evaluation of		DNALIMS
-	911	61	PHO-001	Evaluation of		DNALIMS
-	988	61	PHO-001	Evaluation of		DNALIMS
-	1002	61	PHO-001	Evaluation of		DNALIMS
-	1003	61	PHO-000	Evaluation of		DNALIMS
-	101	61	PHO-001	Evaluation of		DNALIMS

Print **Close**

Fig. 10

Reporting

- ◆ **Multiple Report Types**
 - Genotype Results
 - DNA Integrity
 - Purification Results
 - Sample Lists
 - Audit Trails
- ◆ **Flexible Reporting Output**
 - Using Excel
 - Customized Reporting
 - Using 3rd Party Tools

DNA Purification Results		Sponsor:		Test:		Study #:		Representative:		Investigator(s):	
Study #:	Test:	Storage #	Protocol	Start Vol.	DNA Vol.	Yield	A260	A230	A280	Subject Number	Date of Birth
EA11111	Test	EA11111	0 Sample test	08/06/00	499	0	0	0	0	11kal	5/31/66
EA11112	Test	EA11112	0 Sample test	02/19/00	48	0	0	0	0	21lb	8/26/67
EA11113	Test	EA11113	0 Sample test	08/06/00	248	0	0	0	0	31sc	5/22/66
EA11114	Test	EA11114	0 Sample test	09/06/00	248	0	0	0	0	41mm	4/11/74
EA11115	Test	EA11115	0 Sample test	09/06/00	248	0	0	0	0	51mv	9/9/72
EA11117	Test	EA11117	0 Sample test	09/06/00	248	0	0	0	0	1kal	5/31/66
EA11116	Test	EA11116	0 Sample test	09/06/00	98	0	0	0	0	21lb	8/26/67
EA11118	Test	EA11118	0 Sample test	09/06/00	248	0	0	0	0	31sc	5/22/66
EA11119	Test	EA11119	0 Sample test	09/06/00	582	0	0	0	0	41mm	4/11/74

Fig. 1